UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

NO. 1:11-md-02242-RWZ

IN RE: PROGRAF ANTITRUST LITIGATION

SEALED

ORDER

June 10, 2014

ZOBEL, D.J.

Defendant Astellas Pharma US, Inc. ("Astellas"), maker of the branded tacrolimus drug Prograf, filed a citizen petition with the Food and Drug Administration ("FDA") in 2007 challenging the approval process for generic tacrolimus, a prescription immunosuppressant used in organ transplant patients. Plaintiffs, direct and indirect purchasers of tacrolimus, assert that the petition was objectively baseless and motivated by a scheme by Astellas to unlawfully extend its monopoly in the market for tacrolimus products.[1]

Currently before the court are several motions that are ripe for decision: (1) Indirect Purchaser Plaintiffs' Motion for Reconsideration of Class Certification (Docket # 371); (2) Consolidated Plaintiffs' Motion to Strike Astellas's Designations of Non-Reporting Experts (Docket ## 330 and 332); (3) Astellas's Motion for Summary Judgment on All Claims Against It (Docket # 358); (4) Astellas's Motion for Summary Judgment as to All Claims Made by Plaintiff Judith Carrasquillo (Docket # 308); and (5) Astellas's Motion to Unseal Memorandum of Decision Regarding Class Certification

[1] More detailed background information can be found in the court's prior opinions in the case.

(Docket # 426). I address the pending motions seriatim below.

1. Indirect Purchaser Plaintiffs' Motion for Reconsideration of Class Certification (Docket # 371)

On December 17, 2013, I denied indirect purchaser plaintiffs' ("IPPs") motion for class certification.[2] See Docket # 350. Although the proposed class met the requirements of Fed. R. Civ. P. 23(a), IPPs failed to demonstrate predominance and superiority under Rule 23(b)(3) on the issue of antitrust impact because their methodology could not show widespread injury to class members without the use of individualized data. In their motion for reconsideration, IPPs do not seek to challenge the court's holdings with respect to antitrust impact; rather, they request partial certification of a class only as to the issue of Astellas's alleged antitrust conduct.[3]

Rule 23(c)(4) provides that "[w]hen appropriate, an action may be brought or maintained as a class action with respect to particular issues." The provision enables courts to isolate certain issues for class certification even where other uncommon or unmanageable issues may preclude certification with respect to the case as a whole. See 7AA CHARLES ALAN WRIGHT, ET AL., FEDERAL PRACTICE & PROCEDURE, § 1790 (3d ed. 2005) ("[T]he theory of Rule 23(c)(4)(A) is that the advantages and economies of

[2] IPPs are Louisiana Health Service Indemnity Company d/b/a BlueCross BlueShield of Louisiana ("BCBSLA"), New Mexico United Food and Commercial Workers Union's and Employers' Health and Welfare Trust Fund ("NMUFCW"), Plumbers and Pipefitters Local Union Number 572 Health and Welfare Fund, Janet M. Paone, and Judith Carrasquillo. Summary judgment against NMUFCW was allowed on April 3, 2014, following IPPs' concession that NMUFCW had not suffered injury during the proposed damages period. See Docket ## 437 and 438.

[3] IPPs have not previously sought partial certification of a class in this case. Thus, their motion for "reconsideration" is more accurately viewed as a request that the court exercise its ability to alter or amend the order denying class certification pursuant to Fed. R. Civ. P. 23(c)(1)(C).

adjudicating issues that are common to the entire class on a representative basis may be secured even though other issues in the case may need to be litigated separately by each class member."). Thus, courts can certify classes as to liability only, leaving damages for later individualized determinations. In re New Motor Vehicles Canadian Export Antitrust Litig., 522 F.3d 6, 28 (1st Cir. 2008); Tardiff v. Knox County, 365 F.3d 1, 7 (1st Cir. 2004). Certification can also be of more limited scope, covering specific common issues short of completely resolving liability. See, e.g., Payton v. Abbott Labs, 83 F.R.D. 382, 386-87 (D. Mass. 1979) ("If the plaintiffs win favorable determinations on the class issues, they will not have proved the defendants' liability to class members, but they will have established legal and factual prerequisites to it. Answers to common questions need not guarantee a determination of liability."), vacated on other grounds, 100 F.R.D. 336 (D. Mass. 1983); Fleischman v. Albany Medical Center, No. 1:06-cv-765, 2008 WL 2945993, at *4-7 (N.D.N.Y. July 28, 2008) (granting partial certification as to violation of antitrust law, but not as to injury-in-fact or damages); McQuiklen v. A&R Development Corp., 576 F. Supp. 1023, 1031 (E.D. Pa. 1983) (listing cases holding class certification to be appropriate "where common issues important to the litigation can be resolved on a classwide basis even though the common issues may not be dispositive").

IPPs assert that partial certification is appropriate here because common issues clearly predominate with respect to the first element of an antitrust claim, violation of antitrust law. As noted in the decision denying certification, "[t]he showing necessary to prove a violation in this case – the possession of monopoly power in the relevant

market and the willful maintenance of that power through anti-competitive or exclusionary means – focuses entirely on Astellas's alleged conduct rather than that of individual class members and can be proven through evidence common to the class." Docket # 350 at 21. Thus, all IPP class members, as well as the certified class of direct purchaser plaintiffs, present the same allegations and proof of misconduct by Astellas.

Partial certification offers several legal and practical advantages in this case. Many individual indirect purchaser plaintiffs are unlikely to have the resources or incentive to litigate an entire antitrust case against Astellas on their own; proving antitrust conduct by Astellas, as evidenced by the parties' efforts to date, is a complex and costly endeavor. Even if such separate legal actions are pursued, they are likely to require duplicative discovery and redundant litigation, and may result in inconsistent adjudications regarding Astellas's conduct. In contrast, certifying an issue-specific class here would allow the parties to resolve the question of antitrust violation in one efficient and economical stroke. While a favorable judgment for plaintiffs on antitrust conduct would not, without more, establish Astellas's liability, it would significantly advance each class member's claims; with a violation of antitrust law already determined, class members could then choose to proceed with their claims individually to prove impact and damages. Conversely, a judgment in Astellas's favor would be binding on all class members and foreclose any liability on their claims.[4] See Payton,

[4] Neither party has addressed whether issue preclusion would apply if an issue class is not certified and the question of antitrust violation were adjudicated only as to the named indirect purchaser plaintiffs. While it appears that subsequent plaintiffs could possibly use a verdict against Astellas to prevent relitigation of the issue in future cases, the same would not be true for Astellas in the event it prevails here. See Gunnells v. Healthplan Services, Inc., 348 F.3d 417, 427 (4th Cir. 2003) ("[P]roceeding with individual claims makes the defendant vulnerable to the asymmetry of collateral

83 F.R.D. at 387 ("Victory for the defendants in this action will guarantee them freedom from harassing or repetitive litigation asserting theories and claims that have been disposed of. Victory for the plaintiffs will go far towards bringing them recovery.").

Astellas argues, however, that certification of Rule 23(c)(4) issue is not available because there has not been a showing of predominance as to the cause of action as a whole. As I previously acknowledged in another case, In re Bank of America Home Affordable Modification Program (HAMP) Contract Litigation, M.D.L. No. 10-2193-RWZ, 2013 WL 4759649, at *9 (D. Mass. Sept. 4, 2013), there is disagreement among the federal courts of appeals regarding the use of Rule 23(c)(4). The Fifth Circuit requires that "a cause of action, as a whole, must satisfy the predominance requirement" in order for a class to be certified on any issue. Castano v. Am. Tobacco Co., 84 F.3d 734, 745 n. 21 (5th Cir. 1996). The Second and Ninth Circuits, on the other hand, have held that when plaintiffs seek to certify an issue-specific class, they need only show that common questions predominate as to that particular issue. See In re Nassau Cnty. Strip Search Cases, 461 F.3d 219, 226-27 (2d Cir. 2006) (analyzing the language of subsection (c)(4) and rejecting Castano's interpretation as rendering the provision "virtually null"); Valentino v. Carter-Wallace, Inc., 97 F.3d 1227, 1234 (9th Cir. 1996).

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estoppel: If [defendant] lost on a claim to an individual plaintiff, subsequent plaintiffs could use offensive collateral estoppel to prevent [defendant] from litigating the issue. A victory by [defendant] in an action by an individual plaintiff, however, would have no binding effect on future plaintiffs because the plaintiffs would not have been party to the original suit.") (internal citations omitted); Allen v. McCurry, 449 U.S. 90, 95 (1980) ("[T]he concept of collateral estoppel cannot apply when the party against whom the earlier decision is asserted did not have a 'full and fair opportunity' to litigate that issue in the earlier case.") (citation omitted).

"Collateral estoppel thus is a double-edged sword for a defendant." Coffin v. Bowater Inc., 228 F.R.D. 397 n.13 (D. Me. 2005). Class certification, in contrast, would provide Astellas with "the benefit of finality and repose," Gunnells, 348 F.3d at 427, that issue preclusion cannot, since a victory in this action would apply consistently to all class members' claims grounded in antitrust conduct.

The Third Circuit, in Gates v. Rohm and Haas Co., 655 F.3d 255, 273 (3d Cir. 2011), declined to join either camp and instead followed guidance set forth in the Final Draft of the American Law Institute's Principles of Aggregate Litigation, which recommends that the court consider a number of factors, including, inter alia, the type of claims and issues in question, the complexity of the case, "the efficiencies to be gained by granting certification in light of realistic procedural alternatives," the substantive law of the underlying claims, the impact of partial certification on the rights of the parties, the potential preclusive effect or lack thereof that resolution of the proposed issue class will have, the repercussions of partial certification on the resolution of remaining issues, the impact of individual proceedings upon each other, and the evidence to be presented on the certified issue.

The First Circuit – though yet to take a clear position in the debate – has endorsed the certification of liability-only classes despite individualized damage issues, see Tardiff, 365 F.3d at 6, which suggests it may agree with the more flexible view espoused by the Second and Ninth Circuits or, at the very least, the discretionary test adopted by the Third Circuit. Therefore, and given my determination above that common questions predominate as to the issue of antitrust violation and that partial certification would materially advance the litigation for all parties, I find that IPPs need not demonstrate predominance for the entire action in order to certify an issue-specific class in this case.

Astellas raises additional objections to partial certification: that the proposed class includes members who lack Article III standing, and that bifurcation of IPPs'

claims on antitrust conduct and antitrust impact/damages would violate the Seventh Amendment's Reexamination Clause.

Astellas contends, citing Denney v. Deutsche Bank, 443 F.3d 253, 264 (2d Cir. 2006), that the proposed class cannot be certified here because it includes many members who suffered no injury and therefore lack Article III standing. IPPs counter that courts do not require proof of absent class members' standing in order to certify a class. In support, IPPs point to the Fifth Circuit's recent analysis in In re Deepwater Horizon, 739 F. 3d 790, 800-807 (5th Cir. 2014), of the two primary approaches taken by courts in evaluating standing for the purposes of class certification. The first approach "hinges exclusively on the Article III standing of the 'named plaintiffs' or 'class representatives' . . . [and] requires courts to ignore absent class members entirely." Id. at 800. See also 1 WILLIAM B. RUBENSTEIN, NEWBERG ON CLASS ACTIONS § 2:3 (5th Ed. 2011) ("[P]assive members need not make any individual showing of standing because the standing issue focuses on whether the named plaintiff is properly before the court, not whether represented parties or absent class members are properly before the court."). Under the second approach, demonstrated in Denney, "courts must ensure that absent class members possess Article III standing by examining the class definition," although without "scrutinizing or weighing any evidence of absent class members' standing or lack of standing during the Rule 23 stage." Id. at 801.

Under either approach, I find that IPPs have sufficiently demonstrated standing to proceed at this stage of the litigation. "[T]he presence of one party with standing is sufficient to satisfy Article III's case-or-controversy requirement," Rumsfeld v. Forum for

Academic and Institutional Rights, Inc., 547 U.S. 47, 52 n.2 (2006), and Astellas does not challenge the standing of at least one named IPP plaintiff, BCBSLA. See also 1 RUBENSTEIN, supra at § 2:8 ("So long as at least one class representative has standing, the case may proceed with that party acting as the class's representative."). As for the absent class members, Denney does "not require that each member of a class submit evidence of personal standing," but rather asks whether the class "is defined in such a way that anyone within it would have standing." 443 F.3d at 264. Taking IPPs' allegations as true, all the class members purchased, paid for, or reimbursed for prescription tacrolimus at supracompetitive prices as a result of Astellas' antitrust conduct. Even if closer investigation of any individual class member's claim may ultimately reveal a lack of injury-in-fact,[5] the class as defined does not include obviously uninjured members or members "who concede that they lack any causally related injury." In re Deepwater Horizon, 739 F.3d at 804 (internal quotations omitted). Astellas conflates the showing required for standing with the higher evidentiary showing necessary to actually prevail on claims of injury. "[S]o long as every class member contemplated by the class definition can *allege* standing," the Denney test is satisfied. Id. (internal quotation omitted).

With respect to Seventh Amendment concerns, I find none here. The Seventh Amendment provides that "no fact tried by a jury, shall be otherwise reexamined in any

[5] Indeed, in previously denying class certification, I found that variability in important factors suggested that significant numbers of class members may not have been harmed, and that IPPs had failed to show that their impact methodology could demonstrate widespread harm to the class despite such distinctions. See Docket # 350 at 42-43. This does not mean, however, that the class definition is deficient for standing purposes.

Court of the United States, than according to the rules of the common law." U.S. CONST. amend. VII. Therefore, a court "must not divide issues between separate trials in such a way that the same issue is reexamined by different juries." Matter of Rhone-Poulenc Rorer, Inc., 51 F.3d 1293, 1303 (7th Cir. 1995). Astellas claims that the antitrust violation issue is so intertwined with issues of antitrust impact that splitting them among separate juries would violate the Seventh Amendment. However, as already discussed, litigation on antitrust violation would focus entirely on Astellas's conduct and the state of the tacrolimus market, whereas, assuming such violation, a trial of antitrust impact and damages issues would involve fact-finding regarding whether a particular plaintiff made a tacrolimus purchase at a supracompetitive price and the amount of any overcharges incurred. Such issues are "so distinct and separable" that they can be cleanly divided amongst separate trials "without injustice," Franchi Const. Co., Inc. v. Combined Ins. Co. of America, 580 F.2d 1, 7 (1st Cir. 1978) (quoting Gasoline Products Co. v. Champlin Refining Co., 283 U.S. 494, 500 (1931)); a jury examining the latter can do so without revisiting findings previously made about the former.[6]

Accordingly, IPPs' motion seeking partial class certification on the issue of

[6] Astellas argues that, to prevail on the issue of antitrust violation, IPPs must prove only that Astellas caused *some* delay in the market entry of generic tacrolimus, but the issue of an individual class member's injury would turn in part on a *precise* "but-for" market entry date for generic tacrolimus. Thus, Astellas claims that both juries (one in the trial on antitrust violation, another in the trial on antitrust impact and damages) would need to assess how Astellas's conduct may have impacted generic entry. But this "overlap" can be easily resolved by instructing the first jury to make a specific determination about when generic tacrolimus would have entered the market but for the antitrust conduct. The second jury could then, using that finding, evaluate a plaintiff's injury without having to reexamine Astellas's conduct and its effect on generic market entry.

antitrust violation is ALLOWED.

2. Consolidated Plaintiffs' Motion to Strike Astellas's Designations of Non-Reporting Experts (Docket ## 330 and 332)

Astellas identified nine witnesses as experts for trial, and provided expert reports for four. The remaining five have been designated as "non-reporting" experts under Fed. R. Civ. P. 26(a)(2)(C). Plaintiffs seek to strike the expert designations of four of these non-reporting experts – all transplant physicians – as improper.

Under Rule 26(a)(2)(A), a party must disclose the identity of any witness it may use at trial to present expert testimony or evidence. The rule divides expert witnesses into two categories: (1) if the expert witness is "one retained or specifically employed to provide expert testimony in the case or one whose duties as the party's employee regularly involve giving expert testimony," a detailed written report must accompany the disclosure, Fed. R. Civ. P. 26(a)(2)(B); (2) if no written report is required, then the disclosure must only state the subject matter of the witness's testimony and a summary of the facts and opinions to which the witness is expected to testify, Fed. R. Civ. P. 26(a)(2)(C).

To serve as a non-reporting expert, a witness must have been personally involved in or witnessed the events giving rise to the litigation and his or her expert testimony must be incidental to such involvement. The First Circuit, in interpreting the phrase "retained or specially employed," acknowledged "the difference between a percipient witness who happens to be an expert and an expert who without prior knowledge of the facts giving rise to the litigation is recruited to provide expert opinion

testimony." Downey v. Bob's Discount Furniture Holdings, 633 F.3d 1, 6 (1st Cir. 2011). The plaintiffs in Downey sued a furniture retailer for damages from a bedbug infestation alleged to have arisen from furniture purchased from the defendant. The First Circuit held that an exterminator who had inspected the plaintiffs' home for bedbugs following furniture delivery could testify as an expert witness on the issue of causation without providing a report:

> Like a treating physician – and unlike a prototypical expert witness – [the exterminator] was not retained or specially employed for the purpose of offering expert testimony. Rather, he was 'an actor with regard to the occurrences from which the tapestry of the lawsuit was woven.' Put another way, his opinion testimony arises not from his enlistment as an expert but, rather, from his ground-level involvement in the events giving rise to the litigation.

Id. at 6 (internal citations omitted).

Astellas insists, and plaintiffs strongly dispute, that the four experts at issue are percipient witnesses whose expert opinions arise from personal involvement in the underlying events of this case. Drs. David C. Cronin II, Goran B. Klintmalm, Michael Abecassis, and Benedict Cosimi are all experienced transplant surgeons who, according to Astellas, will offer expert opinions based on their clinical and medical experience – including explanations about the use of narrow therapeutic index drugs in the treatment of transplant patients, various concerns related to switching patients from one formulation of an immunosuppressant to another, and the validity and reasonableness of requests made in Astellas's citizen petition. Drs. Cronin and Klintmalm are also slated to offer opinions as to FDA guidelines and requirements for bioequivalence testing. Plaintiffs contend that none of these proposed experts played

any role in Astellas's decision to draft and file the citizen petition, the actual preparation of the petition, or in the FDA's review of the petition, and thus their opinions are not premised on personal participation in the events giving rise to the litigation.[7] Astellas counters that the objective merit of its petition is at the heart of this case and that the witnesses have personal knowledge, based on their experience as transplant physicians and members of the "transplant community," about the factual underpinnings of that assessment.

Plaintiffs have the better of the argument. Unlike the exterminator in Downey, Astellas's proposed experts were not, for the most part, percipient witnesses to the relevant events in this case; their opinions were not formed during the course of their personal involvement in the citizen petition, but as a result of their "external" experience as transplant physicians. Ground-level involvement with patients or the transplant community is not the same thing as ground-level involvement in the facts and events surrounding the filing of Astellas's citizen petition. Indeed, under Astellas's view, any transplant physician with opinions about immunosuppressants, FDA guidelines, or the petition's validity could conceivably qualify as a percipient non-reporting expert in this case. Such a result is untenable.

Two minor exceptions exist here, however. Drs. Cronin and Klintmalm did have *some* involvement in the citizen petition process. Dr. Cronin submitted a letter to the

[7] Plaintiffs also point out that Astellas previously subpoenaed and deposed Drs. Cronin, Klintmalm, and Abecassis as fact witnesses, and that plaintiffs therefore examined them as such under significant time restraints and without the disclosure of expected testimony. Moreover, at a March 14, 2013 hearing, in the context of a dispute between the parties on reimbursing fact witnesses, Astellas represented that Dr. Cronin is "being deposed as a fact witness." See Docket # 330, Ex. A at 44.

FDA in support of the citizen petition in 2008. Likewise, in 2007, Dr. Klintmalm, as president of American Society of Transplant Surgeons ("ASTS"), signed a letter to the FDA reiterating the requests in Astellas's petition. As such, Drs. Cronin and Klintmalm may testify as fact witnesses regarding their respective letters; to the extent they formed relevant expert opinions during the course of preparing and submitting such letters, they are permitted to offer them. However, they may not testify as to other matters outside that limited scope.

Plaintiffs' motion to strike Astellas's designations of non-reporting experts is ALLOWED IN PART and DENIED IN PART as described above.

3. Astellas's Motion for Summary Judgment on All Claims Against It (Docket # 358)

Summary judgment is appropriate "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). The court must view the record in the light most favorable to the nonmovant and draw all justifiable inferences in that party's favor. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 255 (1986). Astellas seeks summary judgment on all claims brought against it, asserting that plaintiffs cannot prove causation-in-fact or show that the citizen petition was a sham. Plaintiffs argue that important material facts on both issues remain in dispute.

Astellas's citizen petition asked the FDA to: (1) require generic manufacturers of narrow therapeutic index ("NTI") drugs, including tacrolimus, to establish that their formulations are bioequivalent to the brand drug not only in healthy people, but also in

transplant patients (the "Bioequivalence Testing Request"); (2) require certain labeling changes to ensure that doctors and patients are notified when a pharmacy switches a transplant patient from one brand or generic version of an NTI drug to another (the "Notification Request"); (3) require that different versions of such drugs have different appearances so that patients, physicians, and pharmacists can easily distinguish them from one another (the "Source Differentiation Request"); and (4) require that different dosage strengths of such drugs have different appearances (e.g., capsule color) to reduce medication errors (the "Dosage Differentiation Request"). Nearly two years later, the FDA rejected the first three requests but granted the Dosage Differentiation Request. That same day, the FDA approved an Abbreviated New Drug Application ("ANDA") filed by Sandoz, Inc., a generic pharmaceutical manufacturer, for the sale of generic tacrolimus. Plaintiffs accuse Astellas of filing a baseless "sham" citizen petition to foreclose market entry by generic competitors and improperly extend its monopoly on tacrolimus; as a result, generic approval was delayed and, in the interim, plaintiffs paid or reimbursed for tacrolimus purchases at supracompetitive prices.

A. Causation

To prevail on an antitrust claim, a plaintiff "must show that [defendant's antitrust] violation was a 'material cause' of its injury." Addamax Corp. v. Open Software Foundation, Inc., 949 F. Supp. 549, 554 (D. Mass. 1997). "[A] fair degree of certainty is . . . essential to show the causative relation of defendants' misconduct and plaintiff's injury." Id. (quoting Momand v. Universal Film Exchanges, Inc., 172 F.2d 37, 43 (1st Cir. 1948), cert. denied, 336 U.S. 967 (1949)).

Astellas asserts that plaintiffs cannot show that any delay in the FDA's approval of generic tacrolimus was attributable to the unsuccessful citizen petition requests as opposed to the successful (and thus, objectively reasonable) Dosage Differentiation Request. It emphasizes that plaintiffs' causation expert, Martha Bennett, testified that she did not have an opinion as to which of Astellas's four requests may have delayed the FDA's approval of Sandoz's generic tacrolimus. Ms. Bennett gave similar testimony in another pharmaceutical antitrust case, In re Wellbutrin XL Antitrust Litig., Nos. 08-2431, 08-2433, 2012 WL 1657734, at *34 (E.D. Pa. May 11, 2012); when asked if she could state "to any professional certainty" that the citizen petition would have taken less time to resolve had it been limited only to successful requests, the expert responded that she did not know. The court in Wellbutrin granted summary judgment to the defendants due to the plaintiffs' failure to show causation, a result that Astellas insists is likewise required here.

However, in Wellbutrin, the plaintiffs had "not pointed to any other evidence in the record from which a jury could reasonably conclude that the FDA would have approved the ANDAs earlier if the Citizen Petition had been limited to the successful, non-sham requests." Id. In contrast, plaintiffs in this case cite relevant evidence beyond Ms. Bennett's testimony suggesting that at least some, if not all, of the delay was attributable to Astellas' unsuccessful requests. As a preliminary matter, it is evident that the petition itself did indeed delay the FDA's approval of Sandoz's ANDA. See, e.g., Direct Purchaser Plaintiffs' Statement of Facts ("DPPs' SOF") at ¶¶ 197, 201, 218. Plaintiffs argue that the Dose Differentiation Request, though nominally granted,

could not have contributed significantly to that delay because it was an uncontroversial issue with no impact on existing FDA practice or policy. According to plaintiffs, because different strengths of drugs are routinely required to be differentiated, there was no real dispute between the FDA, Astellas, or Sandoz over the practice – certainly not enough to occupy the FDA for two years.[8] Tellingly, the FDA's "approval" of the Dosage Differentiation Request amounts to two sentences expressing agreement with the position, in contrast to the paragraphs and pages devoted to addressing Astellas's other requests. See Docket # 362 at Ex. 9.

Plaintiffs also point to statements made by the FDA indicating that the unsuccessful portions of the citizen petition caused delay. After its petition was largely denied, Astellas brought a lawsuit in the United States District Court for the District of Columbia seeking a temporary restraining order and preliminary injunction requiring the FDA to revoke its approval of generic tacrolimus until the agency reversed its decisions regarding bioequivalence testing, warnings and notifications to physicians and patients, and source differentiation. See DPPs' SOF ¶ 216; Docket # 390, Ex. 215. In opposition, the FDA stated that its delay in approving Sandoz's ANDA was, in part, "directly attributable to the need to evaluate and respond to a citizen petition submitted by Astellas, *raising the same objections* to the approval standards for generic tacrolimus *it has asserted in this lawsuit*." DPPs' SOF ¶ 218; Docket # 390, Ex. 216 at 2

[8] Plaintiffs add that dosage differentiation was particularly a non-issue in the case of tacrolimus. Because Prograf was already dose-differentiated, Sandoz's generic tacrolimus was always intended to be dose-differentiated as well, since FDA regulations required that labels for both brand and generic products be the same.

(emphasis added).

Such evidence is sufficient to raise a genuine issue of material fact as to whether Astellas's allegedly sham requests caused any delay in generic approval beyond the successful request. Summary judgment on the basis of causation is not warranted.

B. Sham Petition

"Those who petition government for redress are generally immune from antitrust liability." Professional Real Estate Investors, Inc. v. Columbia Pictures Industries, Inc., 508 U.S. 49, 56 (1993) ("PRE"). The Noerr-Pennington doctrine "which derives from the First Amendment's guarantee of 'the right . . . to petition the government for redress of grievances,' U.S. Const. amend. I, shields from antitrust liability entities who join together to influence government action – even if they seek to restrain competition or to damage competitors." Davric Maine Corp. v. Rancourt, 216 F.3d 143, 147 (1st Cir. 2000) (citations omitted). Noerr-Pennington immunity is similarly applicable to acts of advocacy before agencies and courts. California Motor Transport Co. v. Trucking Unlimited, 404 U.S. 508, 510 (1972). The doctrine does not apply, however, where a defendant's effort "ostensibly directed toward influencing governmental action, is a mere sham to cover what is actually nothing more than an attempt to interfere directly with the business relationships of a competitor." Eastern R. R. Presidents Conference v. Noerr Motor Freight, Inc., 365 U.S. 127, 144 (1961). The Supreme Court has established a two-pronged inquiry for determining whether the petitioning complained of is a "sham": a plaintiff must show that defendant's petitioning activity is, first,

"objectively baseless," and second, subjectively a concealed attempt calculated to stifle competition. PRE, 508 U.S. at 61.

At issue here is the first prong of the test. Astellas contends that plaintiffs cannot prove that the citizen petition was a sham because its requests to the FDA were not objectively baseless as a matter of law.[9] Under PRE, "objectively baseless" signifies that "no reasonable litigant [or, in this case, petitioner] could realistically expect success on the merits." Id. "If an objective litigant could conclude that the suit [or petition] is reasonably calculated to elicit a favorable outcome, the suit is immunized under Noerr." Id.

Astellas first argues that the petition was not objectively baseless because its requests mirrored longstanding recommendations and concerns of medical experts in the transplantation field. Astellas points to white papers addressing generic substitution of NTI immunosuppressant drugs published by the National Kidney Foundation ("NKF") and the American Society of Transplantation ("AST") in 1999 and 2003, respectively. Both papers recommended bioequivalence testing of generic NTI drugs in patients and noted the importance of informing doctors about switching between different formulations. AST and another prominent American transplantation

[9] The parties offer differing views on the standard of proof on this issue. Astellas, citing CVD, Inc. v. Raytheon Co., 769 F.2d 842, 849-51 (1st Cir. 1985), claims that plaintiffs must prove that the citizen petition was objectively baseless by clear and convincing evidence. Plaintiffs retort that the CVD case is grounded in the unique standards of patent law, and that here, as in most civil litigation, the standard of proof is by a preponderance of the evidence. The Federal Circuit has not yet made explicit the standard of proof for showing objective baselessness under the sham exception to Noerr-Pennington. See, e.g., Wellbutrin, 2012 WL 1657734 at *4-5 (discussing lack of clarity regarding standard). Nonetheless, it is unnecessary to resolve the question here, since I find plaintiffs' evidence sufficient to survive summary judgment under either standard.

society, the American Society of Transplant Surgeons ("ASTS"), along with transplant surgeon Dr. David Cronin, also submitted letters to the FDA echoing the requests made in Astellas's citizen petition. Moreover, Astellas notes that other regulatory agencies have enacted policies and measures that echo those requested in its citizen petition; in 2006, Canada narrowed the acceptable bioequivalence range for NTI drugs and suggested that studies in patients may be necessary, and in 2000, the North Carolina Board of Pharmacy prohibited pharmacists from switching between different formulations of cyclosporine (another NTI drug widely used in transplant patients) without physician notification and patient consent, and required the same for tacrolimus in 2009 after reviewing Astellas's citizen petition.

Plaintiffs, however, raise questions about the reliability and credibility of these recommendations. They allege, citing expert testimony, that the NKF and AST white papers contained no scientific or medical data, but were instead premised on theoretical and unsupported physician concerns. Plaintiffs also present evidence that AST, ASTS, and Dr. Cronin all had significant financial ties to Astellas and that their letters, which plaintiffs argue lacked meaningful scientific data, were prompted – if not entirely ghostwritten – by the company. Similarly, plaintiffs discount the weight of other agency decisions, asserting that Canada's narrowing of bioequivalence ranges for NTI drugs is immaterial since Astellas's petition did not request such changes by the FDA, and the substitution restrictions enacted in North Carolina were not based in data, were insufficient to meet the FDA's statutory standard, and followed intense lobbying and marketing by Astellas.

Astellas also maintains that its requests were reasonable because they addressed unsettled issues of agency policy on which the FDA had specifically requested public comment. See, e.g., Bath Petroleum Storage, Inc. v. Market Hub Partners, L.P., 129 F. Supp.2d 578, 594 (W.D.N.Y. 2000) (in evaluating objective baselessness, noting that defendant "did not initiate the proceeding before [the agency], but rather . . . responded to a public notice issued by [the agency], which invited any person desiring to be heard to file comments or protests."). On May 31, 2007, the FDA announced draft guidance recommending bioequivalence testing of tacrolimus products in healthy people (as opposed to patients) and invited public comment by September 28, 2007. Astellas claims that this invitation – in the context of prior agency statements signaling that, for some drugs, the FDA would be open to requiring bioequivalence testing in patients – indicated that the FDA's draft guidance on tacrolimus was not settled policy, and it therefore responded by filing its citizen petition on September 21, 2007, and written comments on the draft guidance a week later. Given such circumstances, Astellas asserts that a reasonable petitioner could realistically conclude that the FDA was open to modifying its policies on bioequivalence testing for tacrolimus, as requested by the petition.

But here, too, plaintiffs identify disputed questions of fact. They insist that the FDA's bioequivalence testing standards were not unsettled, and that the 2007 guidance on tacrolimus actually reinforced the agency's decades-old standards for testing in healthy subjects. According to plaintiffs, inviting public comment was not an indication by the FDA that it was reconsidering its policies, but simply a mandatory measure

under the Administrative Procedures Act, 5 U.S.C. §§ 551-559. Plaintiffs also cite agency statements and policies showing that the FDA would alter its bioequivalence testing standards only based upon ”well-documented evidence,” which plaintiffs claim Astellas lacked.

As for the scientific merit of the requests themselves, the parties advance starkly different assessments. Astellas argues that the petition sought relief that was well within the ambit of governing FDA regulations and its requests were supported by appropriate materials, including policy concerns and clinical studies about the “switchability” of different formulations of cyclosporine. Plaintiffs counter with expert testimony challenging the studies as scientifically deficient, poorly designed, and inconclusive; in their estimation, the studies clearly fell short of the type of evidence required for the FDA to change its standards. Plaintiffs also accuse Astellas of intentionally concealing a report by the American Medical Association evaluating, among many others, the cyclosporine studies and concluding that “[w]hile concerns still persist among some physicians about the therapeutic equivalence of generic NTI drugs to their brand name innovator products, scientific evidence to support these concerns either does not exist or is very weak.” DPPs’ SOF ¶ 33.

Finally, Astellas claims that the FDA’s responses to its citizen petition, as well as various developments following its filing, confirm that the petition had merit. On March 11, 2008, the FDA sent Astellas an “Interim Response” stating that the petition “raises complex issues requiring extensive review and analysis.” Astellas’s Statement of Undisputed Facts (“Astellas’s SUF”) at ¶ 79-80. A few months later, an FDA official

allegedly was "very complimentary" of the petition to Astellas employees, characterizing it as "excellent." Id. at ¶ 81-82. Astellas also notes the FDA's final response to the petition gave extended consideration to its requests, suggesting that the petition was far from frivolous or baseless but rather raised legitimate issues requiring serious examination. Furthermore, following the denial of the citizen petition, two new clinical studies allegedly demonstrated that switching transplant patients between different tacrolimus formulations may be problematic without follow-up blood monitoring, while another study indicated that a generic form of tacrolimus was not bioequivalent to Prograf in transplant patients. In April 2010, the FDA's Advisory Committee voted that the FDA's current bioequivalence standards were not adequate for NTI drugs, and the agency subsequently revised its draft guidance for tacrolimus to recognize it as an NTI drug and require more rigorous bioequivalence testing. While Astellas admits that the testing changes do not precisely match its requests, it argues they nonetheless show that Astellas's petition was not objectively baseless in asserting that standard bioequivalence testing was not adequate for tacrolimus. More recently, in 2012, the FDA announced that it was funding bioequivalence tests of tacrolimus in patients "to help address the public concerns regarding the quality of generic tacrolimus and improve review practices of generic tacrolimus if necessary." Astellas's SUF ¶¶ 122, 124. Astellas also notes that transplant societies continue to advocate for policies that mirror requests made in the citizen petition and that regulatory authorities around the world have taken action to address concerns that generic NTI immunosuppressant drugs may not be fully substitutable in patients.

In response, plaintiffs argue persuasively that the FDA's responses and post-petition developments do not definitively show that the petition was not a sham.[10] They assert that FDA's interim response was a tentative one issued before full review, the final response explicitly indicated the petition's lack of sufficient scientific or clinical support, and the alleged statements by the FDA official cannot be attributed to the agency. Plaintiffs also point out that the bioequivalence testing changes later adopted by the FDA were not requested in Astellas's petition and therefore are of little relevance to its merit. Plaintiffs' expert, in reviewing the newer clinical studies, concludes that none demonstrate the need for bioequivalence testing in transplant patients. DPPs' SOF, Ex. 225 at ¶¶ 45-54. As for the FDA's 2012 decision to sponsor studies comparing generic and branded tacrolimus, plaintiffs dismiss the move as intended to assuage unsupported public concerns, not driven by scientific ones. Whether or not that is indeed the case, and any resulting significance it may carry with respect to the citizen petition's merit, are questions for the jury.

Based on all the above, I find that material predicate facts remain in dispute about the objective basis for Astellas's requests to the FDA, including the credibility

[10] Plaintiffs generally object to Astellas's use of post-petition evidence to support its motion, arguing that only facts that existed at the time of the petition's filing are relevant. See Filmtec Corp. V. Hydranautics, 67 F.3d 931, 938 (Fed. Cir. 1996) (objective baselessness analysis "requires an inquiry into the reasonableness of the antitrust defendant's litigation when filed."). Astellas, however, notes that courts evaluating objective baselessness have considered scientific and regulatory events occurring after a filing that are consistent with the petition's requests. See, e.g., Louisiana Wholesale Drug Co. v. Sanofi-Aventis, No. 07 Civ. 7343 (HB), 2008 WL 169362, at *5 (S.D.N.Y. Jan. 18, 2008) (subsequent FDA action consistent with petition's request supported jury finding that the petition was not objectively baseless); In re Warfarin Sodium Antirust Litig., No. MDL 98-1232-SLR, 1998 WL 883469, *7 (D. Del. Dec. 7, 1998) (petition not objectively baseless where "FDA later proposed to adopt the very bioequivalency standards recommended by defendant"), rev'd on other grounds, 214 F.3d 395 (3rd Cir. 2000). I will consider post-petition events to the limited extent that they may shed light on the objective reasonableness of Astellas's petition at the time it was filed.

and scientific merit of supporting materials. Accordingly, Astellas's motion for summary judgment as to all claims against it is DENIED.

4. Astellas's Motion for Summary Judgment as to All Claims Made by Plaintiff Judith Carrasquillo (Docket # 308)

Astellas moves separately for summary judgment against indirect purchaser plaintiff Judith Carrasquillo ("Carrasquillo"). It presents two arguments: the first based on the availability of unjust enrichment as a remedy for indirect purchasers under Illinois law, and the second on the merits of Carrasquillo's claim. Because I agree with Astellas on the latter, I need not resolve the former.[11]

To prevail on her claims for unjust enrichment under Illinois law, Carrasquillo must establish that Astellas "has unjustly retained a benefit to [her] detriment." HPI Health Care Servs., Inc. v. Mt. Vernon Hosp., Inc., 545 N.E.2d 672, 679 (Ill. 1989). Carrasquillo also must show Article III standing, that she "has suffered a concrete and

[11] Illinois has adopted, by statute, the Illinois Brick bar to antitrust class action claims by indirect purchasers. See 740 Ill. Comp. Stat. 10/7(2) (2010); Illinois Brick Co. v. Illinois, 431 U.S. 720, 735 (1977). Astellas asserts that Illinois law also precludes an indirect purchaser plaintiff from making an end-run around Illinois Brick and the statute by raising antitrust claims under a theory of unjust enrichment. See, e.g., In re Digital Music Antitrust Litig., 812 F. Supp. 2d 390, 413 (S.D.N.Y. 2011) (dismissing indirect purchaser unjust enrichment claims brought under Illinois law); In re Flonase Antirust Litig., 692 F. Supp. 2d 524, 543 (E.D. Pa. 2010) ("Illinois has adopted the logic of *Illinois Brick*, and therefore Plaintiffs may not assert a claim for unjust enrichment under Illinois law."). Astellas further argues that Illinois law does not allow claims for unjust enrichment to be brought without an independently viable underlying claim. See Martis v. Grinnell Mut. Reinsurance Co., 905 N.E.2d 920, 928 (Ill. App. Ct. 2009).

Carrasquillo strongly disagrees. She contends that Illinois statutory law only prohibits antitrust class actions and does not preclude her from bringing an unjust enrichment claim as a class action. She also disputes that her unjust enrichment claim can simply be dismissed as an end-run around Illinois Brick. See In re G-Fees Antitrust Litig., 584 F. Supp. 2d 26, 46 (D.D.C. 2008) ("No reason or logic supports a conclusion that a state's adherence to the rule of *Illinois Brick* dispossesses a person not only of a statutory legal remedy for an antitrust violation, but also dispossesses the same person of his right to pursue a common law equitable remedy."). Finally, Carrasquillo asserts that Illinois law does provide a stand-alone claim for unjust enrichment and that the Illinois Supreme Court has repeatedly sustained unjust enrichment claims not founded on separate underlying claims. See Raintree Homes, Inc. v. Vill. of Long Grove, 807 N.E.2d 439, 445 (Ill. 2004); Indep. Voters v. Ill. Commerce Comm'n, 510 N.E.2d 850, 856-58 (Ill. 1987); Cleary v. Philip Morris Inc., 656 F.3d 511, 516 (7th Cir. 2011) ("The Illinois Supreme Court appears to recognize unjust enrichment as an independent cause of action.").

particularized injury that is fairly traceable to the challenged conduct, and is likely to be redressed by a favorable judicial decision." Hollingsworth v. Perry, 133 S. Ct. 2652, 2661 (2013).

Carrasquillo claims that she overpaid for Prograf due to Astellas's alleged misconduct in delaying the market entry of generic tacrolimus. Yet Astellas maintains that Carrasquillo cannot prove that she would have paid less for tacrolimus had generic versions been available in September 2008, the date on which she claims Sandoz should have entered the market, rather than in August 2009, the actual date of generic entry. According to IPPs' economist, Dr. Meredith Rosenthal, there were no damages resulting from overcharges after 2009. The inquiry thus focuses on whether Carrasquillo overpaid for her tacrolimus prescriptions during the period between September 2008 and December 2009.

The record shows that Carrasquillo would not have switched from Prograf to generic tacrolimus during the damages period even if generics had been available. Carrasquillo used Prograf continuously from 2000 until July 2012, well after generic entry; indeed, prior to her switch to generic tacrolimus in 2012, her prescriptions included a notation from her physician directing pharmacists not to substitute generics for Prograf. The evidence also indicates that Carrasquillo would not have paid less for her Prograf had generic tacrolimus been available in September 2008. From September 2008 to October 2009, Carrasquillo was insured by Blue Cross Blue Shield of Illinois ("BCBSIL") through her husband's employer and paid a $30 flat co-pay for Prograf, which was classified as a "Tier 2" drug on the plan's formulary both before and

after generic entry. From November 2009 to November 2010, Carrasquillo lost her insurance when her husband lost his job, but received Prograf free of charge from Astellas through its Patient Assistance Program ("PAP"). From November 2010 until her switch to generic tacrolimus in July 2012, Carrasquillo once again was insured by BCBSIL after her husband's re-employment; Prograf was still a Tier 2 drug at that time, though BCBSIL had raised its copay for Tier 2 to $40. Therefore, throughout the damages period, the cost of Prograf to Carrasquillo was the same in the actual world as it would have been in the but-for world with earlier generic market entry.

During briefing for class certification, however, IPPs identified one unique instance in which Carrasquillo purportedly overpaid for Prograf. On October 11, 2009, between the time she lost her insurance and when she began receiving free Prograf via PAP, Carrasquillo allegedly made a single Prograf purchase pursuant to the Medicare Part B program, which required her to pay coinsurance in the amount of 20% of the drug's cost. But the analysis conducted by Dr. Rosenthal indicates that the prescription price of Prograf during the fourth quarter of 2009 in the actual world was $567.79, while its price in the but-for world of earlier generic entry was $585.71 – meaning that Carrasquillo's 20% coinsurance payment would have been *higher* with earlier generic entry than it actually was.

Faced with these unhelpful numbers, Carrasquillo presents yet another theory of harm. She concedes that she was not overcharged for her October 11, 2009 Prograf purchase due to its retail price, but now claims she did suffer an overcharge due to "lost coverage" by PAP. Carrasquillo enrolled in PAP following her October 11, 2009

purchase after being referred to the program by a patient advocate at her hospital. Carrasquillo argues that in the but-for world, she would have benefitted from PAP much earlier, making it likely that she would not have paid anything for her October 11, 2009 purchase. To wit, she alleges that Astellas expanded and promoted PAP as a countermeasure to generic entry and, had generic entry occurred earlier, Astellas would have begun its PAP campaign earlier, leading her to enroll in PAP at least a month sooner.

Carrasquillo's new arguments are highly speculative. Even if Astellas had indeed expanded and promoted PAP in response to generic entry, and would have done so earlier in the but-for world, there is a scant evidence that this would have had any impact on when Carrasquillo enrolled in PAP. Carrasquillo contends that she was "exactly the type of patient Astellas targeted" for PAP and that her enrollment in PAP resulted mainly from the efforts of Astellas and the patient advocate, such that an earlier increased marketing campaign would have led to earlier awareness in the medical community and, consequently, earlier coverage for her.[12] Yet, the record reveals that the impetus for Carrasquillo's enrollment in PAP was her husband's job loss in October 2009 and her resulting loss of insurance; at that point, having paid for her October 11, 2009 prescription via Medicare, Carrasquillo then contacted a hospital social worker, who referred her to the patient advocate. See Docket # 356, Declaration

[12] There is no suggestion that Carrasquillo would not have been eligible for PAP prior to the expansion of its income eligibility criteria. In any event, since the eligibility expansion occurred in the summer of 2009, the changes would already have been in place by October 2009 had she sought to enroll then.

of Ben Keith, Ex. A. There is no indication Carrasquillo would have somehow contacted the social worker for assistance sooner in the but-for world, or that the social worker or patient advocate were previously unaware of PAP prior to the alleged marketing push by Astellas. Likewise, Carrasquillo points to no evidence that she herself would have become personally aware of and applied for enrollment in PAP prior to October 11, 2009 in the but-for world; in fact, at her deposition – occurring years after Astellas's heightened PAP campaign – she testified that she had never heard of the program. Id.

Carrasquillo simply fails to present sufficient evidence that her participation in PAP would have been accelerated by earlier generic entry. As such Astellas's motion for summary judgment as to Carrasquillo is ALLOWED.

5. Astellas's Motion to Unseal Memorandum of Decision Regarding Class Certification (Docket # 426)

The court's December 17, 2013, memorandum of decision denying certification of a class of indirect purchasers (Docket # 350) was issued under seal. Astellas now requests that the memorandum be unsealed and placed on the public docket, asserting that it does not divulge non-public sensitive information or pose a sufficient threat to any party's interests. After reviewing the memorandum, I agree. The motion to unseal is ALLOWED.

CONCLUSION

(1) Indirect Purchaser Plaintiffs' Motion for Reconsideration of Class Certification (Docket # 371) is ALLOWED, and on reconsideration, partial class certification

is ALLOWED on the issue of antitrust violation.

(2) Consolidated Plaintiffs' Motion to Strike Astellas's Designations of Non-Reporting Experts (Docket ## 330 and 332) is ALLOWED IN PART and DENIED IN PART. Drs. Cronin and Klintmalm shall be permitted to testify only as to their involvement in preparing and submitting letters to the FDA in support of Astellas's citizen petition, including any expert opinions incidental to such involvement. The remaining expert designations shall be stricken.

Consolidated Plaintiffs' Motion for Leave to File Reply to Astellas's Memorandum in Opposition (Docket # 338) is ALLOWED.

(3) Astellas's Motion for Summary Judgment on All Claims Against It (Docket # 358) is DENIED. Astellas's assented-to Motion for Leave to File Excess Pages (Docket # 359) is ALLOWED.

(4) Astellas's Motion for Summary Judgment as to All Claims Made by Plaintiff Judith Carrasquillo (Docket # 308) is ALLOWED. Judgment may be entered for Astellas.

(5) Astellas's Motion to Unseal Memorandum of Decision Regarding Class Certification (Docket # 426) is ALLOWED. Astellas's assented-to Motion for Leave to File Reply in Support (Docket # 439) is ALLOWED.

June 10, 2014
DATE

/s/Rya W. Zobel
RYA W. ZOBEL
UNITED STATES DISTRICT JUDGE